

Attorney Docket No. 5470.269  
Application Serial No.: 10/030,529  
Filed: May 6, 2002  
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### REMARKS

Claims 1, 3, 5, 8, 9, 14-18 and 23-25 are pending in the present application. Claims 14-17 are canceled herein without prejudice. Claims 1, 5, 9 and 18 are amended herein for clarity to more particularly define the invention. Support for these amendments is found in the language of the original claims and throughout the specification, as set forth below. The specification is amended herein to address the issues raised by the Examiner as described herein and to correct various inadvertent typographical errors. No new matter is added by these amendments and their entry and examination are respectfully requested. In light of these amendments and the following remarks, applicants request reconsideration and allowance of the pending claims.

Applicants acknowledge that the Office Action states that claim 3 is allowed.

Applicants also acknowledge receipt of an Advisory Action mailed March 27, 2006 in response to the Amendment filed March 14, 2006, which was not entered. Pursuant to a telephone conference on April 13, 2006 between Examiner Devi and applicants' representative, Dr. Mary Miller, the following amendments and remarks are believed to address all of the concerns raised by the Examiner regarding new issues raised by the amendments presented in the March 14, 2006 Amendment. Thus, applicants respectfully request entry of the present Amendment and the issuance of a Notice of Allowance. If, upon review of the present Amendment, the Examiner identifies any remaining issues, applicants respectfully request that the Examiner contact the undersigned directly by telephone before issuing any further Actions in order to expedite the prosecution of this application to allowance.

#### I. Objections

A. The Office Action states that claim 5 is objected to for the recitation of "Claim1" rather than "Claim 1."

Claim 5 is amended herein to correct this inadvertent typographical error, thereby mooted this objection and applicants respectfully request its withdrawal.

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B. The Office Action states that the use of trademarks in the application is noted and that such usage should be according to the proper format for reciting a trademark in a patent application. Specifically, the Office Action points out the recitation of "Adjuvax," "Titermax" and "carbopol" on pages 30-31 and on page 34 and the recitation of "Centrilutor" on pages 38-39 of the specification.

The specification is amended herein to recite these trademarks listed on pages 30-31, 34 and 38-39 in the substitute specification in the proper format. Thus, this objection has been overcome and applicants respectfully request its withdrawal.

## II. Rejection under 35 U.S.C. § 101

The Office Action states that claim 9 is rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter, on the basis that this claim as written does not sufficiently distinguish over cells as they exist naturally. The Examiner suggests that this claim be amended to recite the term "isolated" to overcome this rejection.

As applicants explained in response to the previous Office Action, claim 9 as presented previously recites a cell containing the expression vector of claim 8. Claim 9 depends from claim 8, which recites an expression vector comprising the polynucleotide according to claim 1 and claim 1 recites an isolated polynucleotide. Thus, by virtue of these dependencies, the cell of claim 9 comprises an isolated polynucleotide, thereby distinguishing the cell of claim 9 from a cell as it exists naturally. Thus, using the Examiner's own language, the claims themselves do indeed particularly point out a non-naturally occurring difference between the claimed cell and naturally occurring cells. Thus, claim 9 is not directed to non-statutory subject matter and applicants respectfully maintain that this rejection under 35 U.S.C. § 101 is improper. However, to expedite prosecution of the pending claims to issue, claim 9 is amended herein to recite an isolated cell. Thus, this rejection has been rendered moot and applicants respectfully request its withdrawal.

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### **III. Rejection under 35 U.S.C. § 112, second paragraph**

A. The Office Action states that claims 1, 5, 8, 9, 14-16, 18 and 23-25 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner itemizes these rejections as (a) through (e) in the Office Action and each of these rejections is addressed as follows in this format.

(a and b). The Office Action states that claim 1 is vague in the recitation of "as exemplified by" on line 9, but the Examiner proposes two different amendments to address this rejection. Claim 1 is amended herein to replace "as exemplified by" with "represented by" as proposed in item (b) of this rejection.

(c). The Office Action states that claim 1 is vague, indefinite and/or incorrect in the recitation of "polynucleotides that hybridize....which encode a ....DsrA," and the Examiner suggests amending the claim to recite "a polynucleotide that hybridizes...which encodes a....DsrA." Claim 1 is amended herein to incorporate the suggested language.

(d). The Office Action states that claim 18 is vague, indefinite and/or it lacks proper antecedent basis in the recitation of "DsrA in the biological sample," because it is unclear whether this DsrA is different from the one recited in line 2 of this claim. The Examiner suggests that the claim be amended to recite "the DsrA in the biological sample." Claim 18 is amended herein to incorporate the Examiner's suggestion.

(e). The Office Action states that claims 5, 8, 9, 14-16 and 23-25, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the vagueness or indefiniteness of the base claim. As noted above, claim 1 is amended herein to address the language that the Examiner considers vague, thereby rendering claims dependent therefrom definite and free of this rejection.

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All of the rejections itemized as (a) through (e) in the Office Action have been adequately addressed herein and applicants respectfully request the withdrawal of this rejection.

B. The Office Action states that claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the recitation of the term "fragment." The Examiner proposes some suggested claim amendments to overcome this rejection.

Claim 17 is canceled herein without prejudice, thereby mooted this rejection and applicants respectfully request its withdrawal.

#### **IV. Rejection under 35 U.S.C. § 112, first paragraph**

The Office Action states that claim 18 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. Specifically, the Office Action states that the claim as amended now recited "under conditions whereby a nucleic acid hybridization complex can form if a polynucleotide that encodes DsrA is present in the biological sample," and that this phrase lacks descriptive support in the specification.

Claim 18 is amended herein to delete the phrase that the Examiner considers new matter and now recites the phrase "thereby forming a hybridization complex," as previously presented in claim 18. As the Examiner did not raise any issues about this prior language, applicants believe this amended language is acceptable and respectfully request the withdrawal of this rejection.

#### **V. Rejection under 35 U.S.C. § 102(b)**

The Office Action states that claims 14-16 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Skurnik et al.

Claims 14-16 are canceled herein without prejudice, thereby mooted this rejection and applicants respectfully request its withdrawal.

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In view of the foregoing amendments and remarks, applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$60.00 as the fee for a one month extension of time for a small entity. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this correspondence is being sent by facsimile transmission to central facsimile number 571-273-8300 at the U.S. Patent and Trademark Office and is addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 13, 2006.

  
Amelia Tauchen